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Congress of the United States
House of Representatives

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

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April 11, 2019

Jennifer Orme-Zavaleta, Ph.D.
Principal Deputy Assistant Administrator for Science and EPA Science Advisor
Office of Research and Development
U.S. Environmental Protection Agency
1200 Pennsylvania Ave NW
Washington, DC 20460

Dear Dr. Orme-Zavaleta:

On behalf of the Committee on Science, Space, and Technology, Subcommittee on Investigations & Oversight, and Subcommittee on Environment, we want to express our sincere appreciation for your participation in the March 27, 2019 joint hearing entitled "*EPA'S IRIS Program: Reviewing Its Progress And Roadblocks Ahead.*"

We have attached a transcript of the hearing for your review. The Committee's rule pertaining to the printing of transcripts is as follows:

The transcripts of those hearings conducted by the Committee, when it is decided they will be printed, shall be published in substantially verbatim form, with the material requested for the record inserted at that place requested, or at the end of the record, as appropriate. Individuals, including Members, whose comments are to be published as part of a Committee document shall be given the opportunity to verify the accuracy of the transcription in advance of publication. Any requests by those Members, staff, or witnesses to correct any errors other than errors in the transcript, or disputed errors in transcription, shall be appended to the record, and the appropriate place where the change is requested will be footnoted. Prior to approval by the Chair of hearings conducted jointly with another Congressional Committee, a memorandum of understanding shall be prepared which incorporates an agreement for the publication of the transcript.

Transcript edits, if any, should be submitted by **Wednesday, April 24, 2019**. If no edits are received by the above date, we will presume that you have no suggested edits to the transcript.

We are also attaching questions submitted for the record by Members of the Committee. Please submit answers to all of the enclosed questions no later than **Wednesday, April 24, 2019**.

All transcript edits and responses to questions should be submitted to both of us and directed to the attention of Caitlin Buchanan. If you have any further questions or concerns, please contact Caitlin Buchanan at (202) 225-8500.

Sincerely,

Representative Mikie Sherrill
Chairwoman
Subcommittee on Investigations & Oversight
Committee on Science, Space, and Technology

Representative Lizzie Fletcher
Chair
Subcommittee on Environment
Committee on Science, Space, and Technology

HOUSE COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY
SUBCOMMITTEE ON INVESTIGATIONS & OVERSIGHT

"EPA'S IRIS Program: Reviewing Its Progress And Roadblocks Ahead."

Questions for the Record to:
Jennifer Orme-Zavaleta, Ph.D.
Principal Deputy Assistant Administrator for Science and EPA Science Advisor
Office of Research and Development
U.S. Environmental Protection Agency
Submitted by Subcommittee Chairwoman Mike Sherrill (D-NJ)

- In fall of 2018, David Dunlap assumed the role of deputy assistant administrator of ORD. Around the same time, ORD initiated the second round of the survey process, which you said you had no involvement in, though you had disseminated the first round. Did the process switch from your purview to David Dunlap's, and if so, when? What was his involvement in compiling the December 2018 and the April 2019 Program Outlook documents? What was yours? Was David Dunlap involved in decisions relating to formaldehyde prior to his December 2018 recusal?

- In the April 2019 Program Outlook, EPA lists some chemicals as "discontinued" and some as "suspended." What is the distinction between these classifications? What does it mean that assessments of suspended chemicals may be "restarted as Agency priorities change?" How does this differ from how work on a currently discontinued chemical may be picked up in response to changing priorities?

- According to your testimony, OCHP submitted its final list of priority chemicals for the IRIS survey exactly one day after ORD released a Program Outlook for the IRIS program in December 2018. As a result, ORD did not incorporate OCHP's priorities into the official IRIS Program Outlook. As it was compiling the December 2018 Program Outlook, did ORD make any effort to obtain OCHP's second-round survey response? What internal communications, written or oral, did OCHP receive regarding the timing and/or content of this second-round survey? Which EPA offices and officials communicated with OCHP regarding the IRIS survey, and to whom at OCHP were they communicating?

- In September 2018, the Director of OCHP was placed on Administrative Leave. Please identify the career employee or employees at OCHP who oversaw the compilation of OCHP's final list of priority chemicals for the IRIS survey. Please also identify the official who possessed the ultimate authority to approve OCHP's final list of priority chemicals before it was submitted to ORD.

- What chemicals did OCHP submit on its final priority list for the IRIS survey? Was formaldehyde one of the chemicals that OCHP identified as a priority?

- If OCHP had submitted its final list of priority chemicals for the IRIS survey before December 4, 2018, would its priorities have been included in the IRIS Program Outlook for December 2018? Since OCHP submitted its final list of priority chemicals too late to be considered as a part of the 2018 IRIS survey, will its priorities now be considered immediate nominations for the IRIS program, or as nominations for the next IRIS priority survey? Were these responses considered in ORD's April 2019 Program Outlook?

- According to Dr. Orme-Zavaleta's testimony, the IRIS priority survey will now occur annually. Please elaborate on how ORD plans to conduct the IRIS survey in 2019, and whether any procedures will differ from the process that occurred in 2018. When will the 2019 survey formally begin, and how will ORD ensure that every program office in EPA possesses the opportunity to submit its priorities in time to be considered?

- How much money has been spent over the years in preparing the draft formaldehyde assessment that is reportedly ready to be released for review?

Questions for the Record to:
Jennifer Orme-Zavaleta, Ph.D.
Principal Deputy Assistant Administrator for Science and EPA Science Advisor
Office of Research and Development
U.S. Environmental Protection Agency
Submitted by Representative Don Beyer (D-VA)

- The GAO report issued on March 4, 2019, stated that it was unclear what the IRIS prioritization process was meant to achieve. What was the purpose of the prioritization process? Who was involved in the decision to undertake each step of the prioritization process, from May 2018 through April 2019?

Questions for the Record to:
Jennifer Orme-Zavaleta, Ph.D.
Principal Deputy Assistant Administrator for Science and EPA Science Advisor
Office of Research and Development
U.S. Environmental Protection Agency
Submitted by Representative Bill Foster (D-IL)

Willowbrook Illinois in my district is home to a sterilization facility that used Ethylene Oxide to sterilize medical equipment. This community has unfortunately become an example of the important role the EPA plays in defending public health and what can happen when these systems do not work as they should. In the case of Ethylene Oxide, there was a 15-year gap between the publication of scientific papers that indicated that EtO was a far more powerful carcinogen than had been previously assumed, and the corrective actions and eventual shutdown of the facility in my district that was venting apparently unsafe amounts of EtO into nearby neighborhoods. See Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (CASRN 75-21-8) and references therein.

- What were the reasons for a 15-year delay in this type of situation?
- How much of that delay could have been avoided if the EPA and other relevant regulators had been adequately and fully staffed and funded during this period?
- What is the best estimate of the number of people that will eventually get cancer, nationwide, because of that delay?

Senate Committee on Agriculture, Nutrition & Forestry
Hearing on Hemp Production and the 2018 Farm Bill
July 25, 2019
Questions for the Record
Assistant Administrator Alexandra Dapolito Dunn

Ranking Member Debbie Stabenow

1) Your written testimony indicates that EPA began receiving registration applications for pesticides to be applied to hemp in May of this year, and that there are now 10 such requests pending at EPA. Acknowledging that there are very important statutory and regulatory requirements that the agency needs to comply with to protect human health and the environment, and that these steps can take time, can you please give the committee your best estimate as to when we'll see approved crop protection tools for hemp farmers?

Response: We anticipate taking next steps in the coming months to complete a regulatory decision on each of those actions by the end of 2019.

Senator David Perdue

1) Has EPA approved a label for any restricted use pesticide for hemp?

    a. Is EPA currently considering any applications for such a product? If so, how many?

Response: The Environmental Protection Agency (EPA) has not approved and is not currently considering any applications for restricted-use pesticides for hemp.

2) Does EPA anticipate using the same protocols for establishing future pesticide tolerances for hemp as they would for any other agronomic or food crop?

Response: The EPA will review any pesticide registration application on its merits and in accordance with the pesticide laws and their implementing regulations. Additionally, the EPA and the Inter-regional Research Project #4 (IR-4) are working together to identify the information needed to support tolerance petitions for hemp for conventional pesticides. The EPA and IR-4 met in August 2019 and discussed how to apply these criteria to hemp. We also discussed alternate approaches, including the use of surrogate data from similar crops. We plan to continue to meet with IR-4 to address these issues.

3) Will all risk procedures be followed? Can EPA assure members of this committee that regulators will not relax these procedures simply because of the novelty of this new crop?

Response: The EPA is reviewing applications for use on hemp as we would any other application.

The EPA has received requests for labeling amendments to add hemp as a use site to existing products that have established tolerance exemptions. The products have very low toxicity and do not require updates to the human and ecological risk assessments. In the future, if the EPA receives requests under the Pesticide Registration Improvement Act (PRIA) for products that require a more extensive evaluation, the EPA will ensure that any new uses will meet the safety standards as defined for new registrations in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and for pesticide tolerances on foods (such as hemp seed) in the Federal Food, Drug, and Cosmetic Act (FFDCA).

4) How long do you expect the approval process to be for a hemp-approved pesticide? Is this time period standard for any other crop?

Response: The time period is the same as it would be for any other new use.

The length of time for approving a new use on any crop varies, but is generally defined by PRIA and depends on the extent of review needed. Some applications, however, such as the 10 amendments currently undergoing EPA review, do not fall under PRIA because they have an existing tolerance exemption. If the risk profile lends itself to an expedited review, we will do so, as we would for any pesticide registration application. Information on the length of time for reviews may be found at https://www.epa.gov/pria-fees/fy-2019-fee-schedule-registration-applications.

Senator Deb Fischer

1) We have towns that are concerned about materials that might be released from hemp storage areas or processing facilities.

    a. Will any guidance be provided for processor and/or growers regarding effluents or other waste materials?

Response: Existing regulations on waste management from pesticide products would apply to any registration we approve. Pesticide labels typically have disposal instructions related to the pesticide product. The EPA has no current plans to issue guidance on hemp processing effluent. If hemp processing involves a process wastewater discharge, then the permitting authority would implement the appropriate National Pollutant Discharge Elimination System (NPDES) permitting process. Hemp processing could fall under Category Eleven (xi) – light manufacturing – for industrial stormwater. If storage or other activities were exposed to precipitation and there were stormwater discharges to waters of the U.S., then industrial stormwater permit coverage could be appropriate.

Senator Michael Bennet

1) One of the biggest barriers to hemp production is the lack of EPA-approved pesticides and herbicides. Colorado hemp farmers would like EPA to work quickly to identify products that can be applied to their crops safely.

    a. What steps is the EPA taking to approve hemp pesticides and herbicides quickly?

Response: The EPA is working on a variety of approaches so that we can quickly approve crop protection tools for hemp growers. The EPA is encouraging the submission of requests for products that have a favorable risk profile and therefore have a much shorter review period under PRIA. With respect to potential use of conventional pesticides that require a more extensive evaluation of risk, the EPA is working with states, registrants, and our federal partners to learn more about pest concerns, how and where hemp is grown, and how it is processed, so that we can quickly assess requests while still ensuring that the products meet the applicable regulatory standards.

    b. What steps is the EPA taking to expedite hemp research protocols to update test guidance documents and determine what type of data may still be required?

Response: Current test guidelines do not need to be updated to address hemp. EPA test guidelines already outline the criteria for the types of tests needed for determining how people could be exposed to pesticide residues in hemp products. The EPA and IR-4 are working together to identify the information needed to support tolerance petitions for hemp for conventional pesticides. The EPA and IR-4 held a technical working group meeting in August 2019, and discussed how to apply these criteria to hemp. We also discussed alternate approaches, including the use of surrogate data from similar crops. The EPA and IR-4 plan to continue to meet to address these issues.

    c. Will you work with the state of Colorado in the registration process to identify and approve much needed tools to address pest issues that hemp growers are facing?

Response: The EPA will continue to collaborate with the states, including Colorado, on these issues. The EPA had a call with IR-4, the state of Colorado, and other states in July 2019, to discuss these issues, and additional discussions are anticipated.

HOUSE COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY
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"EPA's IRIS Program: Reviewing Its Progress And Roadblocks Ahead"

Questions for the Record to:
Jennifer Orme-Zavaleta, Ph.D.
Principal Deputy Assistant Administrator for Science and EPA Science Advisor
Office of Research and Development
U.S. Environmental Protection Agency

Submitted by Subcommittee Chairwoman Mikie Sherrill (D-NJ)

1. In the fall of 2018, David Dunlap assumed the role of deputy assistant administrator of ORD. Around the same time, ORD initiated the second round of the survey process, which you said you had no involvement in, though you had disseminated the first round. Did the process switch from your purview to David Dunlap's, and if so, when? What was his involvement in compiling the December 2018 and the April 2019 Program Outlook documents? What was yours? Was David Dunlap involved in decisions relating to formaldehyde prior to his December 2018 recusal?

A: In her role as Principal Deputy Assistant Administrator of the Office of Research and Development (ORD), Dr. Jennifer Orme-Zavaleta was not involved in the second round of prioritization; ORD received the final lists of program office priority assessments. As such, Principal Deputy Assistant Administrator Orme-Zavaleta cannot speak to ORD Deputy Assistant Administrator David Dunlap's involvement in the second round of prioritization or decisions relating to formaldehyde.

Principal Deputy Assistant Administrator Orme-Zavaleta, at the direction of then-Acting Administrator Wheeler, in a request dated August 10, 2018, established a more formal, structured process for identifying IRIS priorities. This process included a requirement that all IRIS priorities be approved by the program's Assistant Administrator. This initial formalized prioritization process was completed in December 2018, and it is bringing further stability and responsiveness to the IRIS program.

Through this new process, EPA programs and regions can formally identify what assessments are a priority program need, why the assessment is needed, and when the assessment is needed. As detailed in the December 4, 2018 memorandum from Principal Deputy Assistant Administrator Orme-Zavaleta, ORD consolidated the program and region input on high priority assessment needs and presented this to the Agency's Assistant Administrators and Deputies. The April 2019 Program Outlook was posted by IRIS program staff and reflected the priority assessments identified in December 2018.

2. In the April 2019 Program Outlook, EPA lists some chemicals as "discontinued" and some as "suspended." What is the distinction between these classifications? What does it mean that assessments of suspended chemicals may be "restarted as Agency priorities change?" How does this differ from how work on a currently discontinued chemical may be picked up in response to changing priorities?

A: "Discontinued" assessments are those for which the IRIS program is not planning to develop new or updated assessments at this time. This means that we do not anticipate these to become Agency IRIS priorities in the near future. These include hexabromocyclododecane (HBCD), acrylonitrile, n-butyl alcohol, and phthalates (butyl benzyl phthalate, dibutyl phthalate, diethyl phthalate, di-isobutyl phthalate, and di-isononyl phthalate).

"Suspended" assessments are those that have been placed on hold and may be restarted as Agency priorities change. This means that we are prepared for future Agency needs. The assessments suspended in the April 2019 Program Outlook include ammonia, chloroform, ethylbenzene, formaldehyde, manganese, naphthalene, nitrite/nitrate, PAH mixtures, and uranium.

Draft assessment materials previously released on the IRIS program website will remain accessible for reference on individual chemical pages. Additionally, existing toxicity values found on IRIS will remain available for use. More information about these chemicals can be found on the IRIS program website.

3. According to your testimony, OCHP submitted its final list of priority chemicals for the IRIS survey exactly one day after ORD released a Program Outlook for the IRIS program in December 2018. As a result, ORD did not incorporate OCHP's priorities into the official IRIS Program Outlook. As it was compiling the December 2018 Program Outlook, did ORD make any effort to obtain OCHP's second-round survey response? What internal communications, written or oral, did OCHP received regarding the timing and/or content of this second-round survey? Which EPA offices and officials communicated with OCHP regarding the IRIS survey, and to whom at OCHP were they communicating?

A: Because IRIS assessments play a critical role in supporting Agency decisions and can involve a significant expenditure of time and resources, Principal Deputy Assistant Administrator Orme-Zavaleta, at the direction of then-Acting Administrator Wheeler, in a request dated August 10, 2018, established a more formal, structured process for identifying IRIS priorities. This process included a requirement that all IRIS priorities be approved by the program's Assistant Administrator. This initial formalized prioritization process was completed in December 2018, and it is bringing further stability and responsiveness to the IRIS program.

Through this new process, EPA programs and regions can formally identify what assessments are a priority program need, why the assessment is needed, and when the assessment is needed. As detailed in the December 4, 2018 memorandum from Principal Deputy Assistant Administrator Orme-Zavaleta, ORD consolidated the program and region input on high priority assessment needs and presented this to the Agency's Assistant Administrators and Deputies. Based on that input, this prioritization process identified eleven priority chemicals: hexavalent chromium, inorganic arsenic, mercury salts, methylmercury, polychlorinated biphenyl (PCBs), five per- and polyfluoroalkyl substances (PFAS), and vanadium. The IRIS program will conduct this same formal request and prioritization process annually, but programs and regions are still able to identify and nominate additional chemicals at any time.

4. In September 2018, the Director of OCHP was places on Administrative Leave. Please identify the career employee or employees at OCHP who oversaw the compilation of OCHP's final list of priority chemicals for the IRIS survey. Please also identify the official who possessed the ultimate authority to approve OCHP's final list of priority chemicals before it was submitted to ORD.

A: Because IRIS assessments play a critical role in supporting Agency decisions and can involve a significant expenditure of time and resources, Principal Deputy Assistant Administrator Orme-Zavaleta, at the direction of then-Acting Administrator Wheeler, in a request dated August 10, 2018, established a more formal, structured process for identifying IRIS priorities. This process included a requirement that all IRIS priorities be approved by the program's Assistant Administrator. This initial formalized prioritization process was completed in December 2018, and it is bringing further stability and responsiveness to the IRIS program.

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5. What chemicals did OCHP submit on its final priority list for the IRIS survey? Was formaldehyde one of the chemicals that OCHP identified as a priority?

A: Because IRIS assessments play a critical role in supporting Agency decisions and can involve a significant expenditure of time and resources, Principal Deputy Assistant Administrator Orme-Zavaleta, at the direction of then-Acting Administrator Wheeler, in a request dated August 10, 2018, established a more formal, structured process for identifying IRIS priorities. This process included a requirement that all IRIS priorities be approved by the program's Assistant Administrator. This initial formalized prioritization process was completed in December 2018, and it is bringing further stability and responsiveness to the IRIS program.

Through this new process, EPA programs and regions can formally identify what assessments are a priority program need, why the assessment is needed, and when the assessment is needed. As detailed in the December 4, 2018 memorandum from Principal Deputy Assistant Administrator Orme-Zavaleta, ORD consolidated the program and region input on high priority assessment needs and presented this to the Agency's Assistant Administrators and Deputies. Based on that input, this prioritization process identified eleven priority chemicals: hexavalent chromium, inorganic arsenic, mercury salts, methylmercury, polychlorinated biphenyl (PCBs), five per- and polyfluoroalkyl substances (PFAS), and vanadium. The IRIS program will conduct this same formal request and prioritization process annually, but programs and regions are still able to identify and nominate additional chemicals at any time.

6. If OCHP had submitted its final list of priority chemicals for the IRIS survey before December 4, 2018, would its priorities have been included in the IRIS Program Outlook for December 2018? Since OCHP submitted its final list of priority chemicals too late to be considered as a part of the 2018 IRIS survey, will its priorities now be considered immediate nominations for the IRIS program, or as nominations for the next IRIS priority survey? Were these responses considered in ORD's April 2019 Program Outlook?

A: OCHP submitted priorities after the list of priority IRIS assessments had been finalized. This final list informed the April 2019 Program Outlook.

The EPA will conduct its annual IRIS priority survey later this year. At that time, EPA program offices will have the opportunity to formally nominate their priority chemicals, but program offices may nominate a chemical for IRIS at any time.

7. According to Dr. Orme-Zavaleta's testimony, the IRIS priority survey will now occur annually. Please elaborate on how ORD plans to conduct the IRIS survey in 2019, and whether any procedures will differ from the process that occurred in 2018. When will the

2019 survey formally begin, and how will ORD ensure that every program office in EPA possesses the opportunity to submit its priorities in time to be considered?

A: Through ORD, the Agency will conduct its IRIS priority survey annually and plans to begin this process in summer 2019. The EPA plans to conduct this process similar to that which occurred in August 2018, with a memo from ORD leadership to the EPA program offices. The memo will include the standardized prioritization template for nominating IRIS assessments, and the memo will clearly state the purpose, type of assessment needed, and deadlines. This will ensure every program office has the opportunity to submit its priorities.

8. How much money has been spent over the years in preparing the draft formaldehyde assessment that is reportedly ready to be released for review?

A: Formaldehyde, because of the complexity and volume of data, is primarily an FTE investment. In addition to the FTE investment, EPA costs associated with IRIS assessments include workshops, contractor support, and NAS peer review, among other expenses.

<u>Submitted by Representative Don Beyer (D-VA)</u>

9. The GAO report issued on March 4, 2019, stated that it was unclear what the IRIS prioritization process was meant to achieve. What was the purpose of the prioritization process? Who was involved in the decision to undertake each step of the prioritization process, from May 2018 through April 2019?

A: IRIS assessments play a critical role in supporting Agency decisions and can involve a significant expenditure of time and resources. Because of the IRIS program's importance, IRIS program staff initiated a review of IRIS priorities at the staff level in May 2018. Then-Acting Administrator Wheeler requested a more formal, structured survey of IRIS priorities in July to be signed at the Assistant Administrator level. This formalized prioritization process was completed in December 2018, and it is bringing further stability and accountability. Through this new process, EPA programs formally identify what assessments are a priority program need, why the assessment is needed, and when the assessment is needed. Not only does this improve the scope of IRIS assessments and help the IRIS program prioritize its activities, it also reinforces accountability between the requesting program and the IRIS program.

Through ORD leadership, the Agency initiated the first survey of IRIS program priorities in August 2018. ORD was not involved in the EPA program offices' further prioritization efforts.

Submitted by Representative Bill Foster (D-IL)

Willowbrook Illinois in my district is home to a sterilization facility that used Ethylene Oxide to sterilize medical equipment. This community has unfortunately become and example of the important role the EPA plays in defending public health and what can happen when these systems do not work as they should. In the case of Ethylene Oxide, there was a 15-year gap between the publication of scientific papers that indicated that EtO was a far more powerful carcinogen than had been previously assumed, and the corrective actions and eventual shutdown of the facility in my district that was venting apparently unsafe amounts of EtO into nearby neighborhoods. See Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (CASRN 75-21-8) and references therein.

10. What were the reasons for a 15-ear delay in this type of situation?

A: The IRIS ethylene oxide assessment, which was initiated in 2002, took about 15 years to complete because of the complexity of the data that needed to be evaluated, as well as the peer review process to which this assessment was subjected. The current assessment reflects the IRIS program's evaluation of the best available science published through 2015 on the health hazards associated with ethylene oxide exposure.

Ethylene oxide is a chemical with a large and robust literature of human epidemiology data. These data are often more complex and time-consuming to analyze compared with data from animal studies. Moreover, the EPA needed to gain access to the original data from one of the key epidemiology studies to conduct specific analyses recommended by external peer reviewers. During the first peer review conducted by the EPA's Science Advisory Board (SAB) in 2006, the reviewers specifically recommended that the EPA conduct original dose-response modeling of the individual epidemiology data using approaches that EPA had not previously used. This recommendation resulted in a significant amount of new work in revising the assessment. Then, given the significant additional modeling of the epidemiologic data, the revised assessment underwent a second peer review in 2012, because the EPA was aware of the critical importance of ethylene oxide, both in terms of its potential human health risk and its importance as a sterilization agent and a feedstock chemical. It is important to note that the ethylene oxide assessment is somewhat unique and that since 2016, the EPA has significantly streamlined its assessment development processes and timelines.

11. How much of that delay could have been avoided if the EPA and other relevant regulators had been adequately and fully staffed and funded during this period?

A: Ethylene oxide is a chemical with a large and robust literature of human epidemiology data. These data are often more complex and time-consuming to analyze compared with data from animal studies. Moreover, the EPA needed to gain access to the original data from one of the key epidemiology studies to conduct

specific analyses recommended by external peer reviewers. During the first peer review conducted by the EPA's Science Advisory Board (SAB) in 2006, the reviewers specifically recommended that the EPA conduct original dose-response modeling of the individual epidemiology data using approaches that the EPA had not previously used. This recommendation resulted in a significant amount of new work in revising the assessment. Then, given the significant additional modeling of the epidemiologic data, the revised assessment underwent a second peer review in 2012, because the EPA was aware of the critical importance of ethylene oxide, both in terms of its potential human health risk and its importance as a sterilization agent and a feedstock chemical. It is important to note that the ethylene oxide assessment is somewhat unique and that since 2016, the EPA has significantly streamlined its assessment development processes and timelines.

12. What is the best estimate of the number of people that will eventually get cancer, nationwide, because of that delay?

A: An IRIS assessment addresses only the first two (of four) steps of the risk assessment process; the reference values derived in an IRIS assessment describe the quantitative relationship between dose or concentration and the effect. An IRIS assessment alone cannot be used to predict health risk (or number of cases of cancer) in a population.